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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
DIAMOND, ALAN D	

ART UNIT	PAPER NUMBER
1753	

DATE MAILED: 03/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/052,601	ROBERT, FREDERIC	
	Examiner	Art Unit	
	Alan Diamond	1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 December 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 8-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 8-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 December 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Comments

1. The Examiner acknowledges receipt of replacement sheets for drawing sheets 1-5. Accordingly, the objection to the drawings is now moot.

2. The Examiner acknowledges that claims 6 and 7 have been cancelled.

3. The 35 USC 112, second paragraph, rejection of claim 19 has been overcome by Applicant's amendment of the claim.

4. The art rejections of claim 1 and its dependent claims over Grushka et al (U.S. 5,660,701) are now moot because Grushka et al does not teach or suggest any of the biological buffers now recited in claim 1.

5. Upon reconsideration, the art rejection based on Lauer et al in view of Alter et al are expressly withdrawn by the Examiner. Lauer et al does not lead a skilled artisan to analyzing a clinical sample containing the claimed protein constituents using the claimed biological buffer. In Lauer et al's Figures 1 and 2, results are provided using CAPS and CHES buffers, which are within the scope of the instant biological buffers. However, the samples analyzed by Lauer et al are not clinical, but rather, are artificial mixtures of model proteins. Lauer et al is silent concerning clinical samples. While some of the proteins in Lauer et al's Table I are within the scope of the instant protein constituents, many are not, and none of the proteins in said Table I is ever analyzed in a clinical sample. Alter et al does not solve Lauer et al's problem because Alter et al, as noted by Applicant on pages 9-10 of the Remarks filed December 20, 2004, uses a

borate buffer that does not lead a skilled artisan to the instant biological buffer. Indeed, Alter et al teaches the use of TES buffer, which has a pKa of 7.5 (see col. 6, line 3).

Claim Objections

6. Claim 4 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 4 does not further limit parent claim 1 because the protein constituents listed in parent claim 1 are blood proteins. Thus, the recitation in claim 4 that the protein constituents are blood proteins does not further limit was is already inherently present in claim 1.

7. Claims 1, 18, 26, and 28 are objected to because of the following informalities: In claim 1, at line 3, and in claim 28, at line 3, the term "albumin or" should be changed to "albumin,". In claim 1, at line 16 (i.e., the second-to-last line), a semicolon should be inserted after "(CABS)". In claim 18, at line 4, the term "alkylimono-" should be changed to "alkyl mono-". In claim 26, at line 4, the period after the word "fluid" should be changed to a comma. In claim 26, at line 8, the word "include" should be changed to "includes". In claim 26, at line 9, the period after the word "groups" should be changed to a comma. Appropriate correction is required.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claim 27 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In claim 27, at line 10, the term "and mixtures thereof" for the biological buffers listed in the Markush group in said claim 27, is not supported by the specification, as originally filed. It is suggested that said term be deleted.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claim 28 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 28 is indefinite because parent claim 26 requires that the clinical sample comprises a human biological liquid selected from serum, plasma, urine, or cerebro-spinal fluid. Thus, in claim 28, it is not clear how the clinical sample can merely be a protein constituent. It is suggested that the term "said clinical sample is a protein constituent from human biological liquids" at lines 1-2 of claim 28 be changed to "a protein constituent in said clinical sample is".

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 26 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Grushka et al, U.S. Patent 5,660,701.

Grushka et al analyzes drug free normal serum using free solution capillary electrophoresis in a capillary tube containing 25 mM glycine buffer, i.e., instant zwitterionic buffer (pKa of 9.8), 25 mM of NaCl (which reads on the instant additive that increases ionic strength), wherein the buffer pH has been adjusted to 11 using NaOH (instant pH-modifier) (see col. 2, lines 20-32; and Example 1 at cols. 4-5). The protein constituents that are separated by migration and detected are albumin, gamma globulin, β-globulin, α_1-globulin, and α_2-globulin (see col. 5, lines 5-9). Since Grushka et al teaches the limitations of the instant claims, the reference is deemed to be anticipatory.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. Claims 1, 3, 4, 8-11, 16, 17, and 22-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keo et al, U.S. Patent 5,599,433.

Keo et al teaches the capillary zone electrophoresis (CZE) of glycosylated proteins in clinical specimens, wherein the buffer system contains, for example, 100 mM CAPS (which reads on the instant biological buffer), 300 mM sodium borate (which

reads on the instant additive that increases ionic strength), and NaOH for adjusting the pH to 11 (see col. 3, lines 32-55; col. 4, lines 43-49; col. 5, line 16 through col. 6, line 14; and col. 8, lines 32-43). The clinical specimen can be a human biological liquid such as serum, plasma, cerebrospinal fluid, urine, etc (see col. 6, lines 17-22). These biological liquids inherently contain the instant albumin, or α_1-globulin, α_2-globulin, β-globulin, β_1-globulin, β_2-globulin, and γ-globulin. The sodium borate concentration can be 50 to 200 mM (see col. 5, lines 43-65). Keo et al teaches the limitations of the instant claims other than the difference which is discussed below.

Keo et al does not specifically require that said buffer system containing, for example, 100 mM CAPS, 300 mM sodium borate, and NaOH be used for the serum, plasma, cerebrospinal fluid, or urine biological fluid. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used said buffer system containing 100 mM CAPS, 300 mM sodium borate, and NaOH for the serum, plasma, cerebrospinal fluid, or urine biological fluid because such is clearly within the scope of Keo et al's disclosure.

Double Patenting

16. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

17. Claims 1-4 and 8-29 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25, 27-30, and 33 of copending Application No. 10/052,931. Although the conflicting claims are not identical, they are not patentably distinct from each other because in claim 23 of said copending application, the buffer can be a zwitterionic biological buffer. As seen in the specification of said copending application the "zwitterionic biological buffer" encompasses buffers such as CAPS.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

18. Applicant's arguments filed December 20, 2004 have been fully considered but they are not persuasive.

Applicant argues that Grushka et al does not teach the biological buffers of claim 26, and that Grushka et al suggests that preferably no other buffering agents other than amino acids be used. However, this argument is not deemed to be persuasive because claim 26 recites "a biological buffer which is zwitterionic with a pKa at 25°C in the range of 8.8 to 10.7 and which includes amine and acid functional groups". This biological buffer includes, for example, the glycine (amino acid) buffer used by Grushka et al. Glycine has amine an acid function groups, is zwitterionic, and has a pKa of 9.8.

Applicant argues that Keo et al does not teach analyzing the clinical sample comprising the protein constituents now reflected in claim 1 and in new claims 26 and 28. However, this argument is not deemed to be persuasive because Keo et al teaches that its clinical specimen can be can be a human biological liquid such as serum, plasma, cerebrospinal fluid, urine, etc (see col. 6, lines 17-22). These biological liquids inherently contain the instant albumin, or α_1-globulin, α_2-globulin, β-globulin, β_1-globulin, β_2-globulin, and γ-globulin.

Conclusion

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alan Diamond whose telephone number is 571-272-

1338. The examiner can normally be reached on Monday through Friday, 5:30 a.m. to 2:00 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen can be reached on 571-272-1342. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Alan Diamond
Primary Examiner
Art Unit 1753

Alan Diamond
March 7, 2005